December 18, 1978

UNITED STATES
NUCLEAR REGULATORY COMMISSION

SECY-78-667

POLICY SESSION ITEM

For: The Commissioners

From: L. V. Gossick
Executive Director for Operations

Subject: NRC ACTION ON NARM TASK FORCE RECOMMENDATION

Purpose: To provide the Commission with further analysis and a revised NMSS position on the NARM Task Force recommendations.

Discussion: In April 1978 the staff briefed the Commission on the final recommendations of the Task Force on Naturally Occurring and Accelerator-produced Radioactive Materials (NARM). The Commission did not take any action on the paper (SECY-78-211), but asked the staff to resubmit it for reconsideration after addressing questions about the magnitude of NARM overexposures, the compatibility of the proposed NRC regulatory authority with other agencies, and other issues.

The staff response to those questions is contained in a draft paper included as Enclosure #1. The staff continues to recommend that NRC seek legislative authority over NARM. The Director of NMSS did not concur in the staff paper. In a separate paper, included as Enclosure #2, the Director, NMSS, recommended that NRC:

1. Forward the Task Force findings to the Congress, Federal agencies and State Governors;

2. Offer to assist others in developing model control programs; and

3. Review NARM control programs after several years to determine further appropriate NRC action.

Contact:
R. Lawrence Vandenberg, MPA
49-27721

OTNI-1
NARM

Discussion: (Continued) I believe there are three major issues to be considered in determining what action should be taken.

1. Risk to Public Health and Safety

   The consensus is that there are risks to the public health and safety from NARM and that these risks could be reduced through nationwide uniform regulation. However, the available data appear insufficient either to determine the magnitude of the problem or estimate the value to the public of Federal regulation of NARM.

2. Scope and Cost of Regulatory Control

   The boundaries of an effective regulatory program for NARM may be broader than those suggested by the task force recommendation. For example, both the NARM task force and R. Cunningham in his memo to Dr. Smith (in Enclosure #2) question whether accelerator-produced material can be adequately regulated without also regulating the accelerators. Currently, NRC is not organized to deal with accelerator safety issues.

   Regarding cost, Dr. Smith believed that the NRC resource requirement to regulate NARM may be far in excess of the seven professional staff years estimated in SECY-78-211. The needed NRC resources cannot be accurately determined because the scope of the problem (including undefined start-up problems) is not well defined. Further, the issue of costs incurred by industry and the public to comply with new regulations has not been addressed.

3. Federal Regulatory Conflict and NRC's Role

   The task force identified twenty-two Federal agencies having some NARM regulatory authority. Nonetheless, several of the agencies have declined to issue regulations. The task force reported that the Consumer Products Safety Commission, for example, has not determined that any NARM article is sufficiently hazardous to warrant control. The reasons for taking this position need to be further explored. In addition, we have received comments on the task force report from only seven of the twenty-two agencies. Of the seven, two (EPA and FDA) expressed some objection to the recommendation. This argues for more extensive discussion among the involved agencies.

NRC's role also needs to be clarified. The issue has been raised that by taking on NARM regulation, NRC may add general radiation protection functions to our primary role of national regulation of the nuclear fuel cycle. Yet from the public health and safety standpoint, the hazards from NARM do not differ substantially from those of material already regulated by NRC (except fissile material). The issue of the appropriate NRC role probably cannot be decided apart from the other issues. Rather, the issue needs to be examined in conjunction with a better definition of the full scope of any needed regulatory program, the resources required and resolution of current Federal regulatory overlap.

As a result, I conclude that the NARM question is not yet well enough defined for a Commission decision on the task force recommendation. What is needed is a value-impact analysis to resolve the first two issues (Public Health and Safety Risk, Scope and Cost of Regulatory Control) and extensive coordination with other agencies, OMB, Congressional Committees and States to resolve the apparent regulatory overlap. In particular, the value-impact analysis should contain alternative regulatory boundaries (i.e., whether or not to include accelerator regulation) and alternative regulatory structures to meet the defined regulatory scope.

Since these tasks may require substantial resources and high level government coordination, Commission policy guidance is needed in the following areas:

1. Should NRC take the lead in preparing a complete value-impact analysis or should we request that OMB, Congressional staff or an interagency group head up this task?

2. In the interim, what position should NRC take in terms of assisting other Federal and State agencies in developing model control programs?

3. Should the task force report (recommending that NRC seek legislative authority over NARM) be sent for comment to higher level officials in Federal and State governments than was already done at the time of the Federal Register notice in July 1977?

If you feel a Commission meeting on this subject will be of value, I will have the staff present their views.

Lee V. Gossick
Executive Director for Operations

Enclosures:
1. Proposed staff paper entitled, "Staff Responses to Commissioner Comments on the Final Recommendations of the Task Force on Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (SECY-78-211) (SECY Memo dated June 30, 1978)"

2. Proposed staff paper entitled, "NMSS Position on Recommendations of Task Force on Regulation of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) (SECY-78-211)"

This paper is tentatively scheduled for consideration at an Open Meeting during the Week of January 15, 1979. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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ENCLOSURE 1

For: The Commissioners

From: Lee V. Gossick
Executive Director for Operations

Subject: STAFF RESPONSES TO COMMISSIONER COMMENTS ON THE FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM) (SECY-78-211) (SECY MEMO DATED JUNE 30, 1978)

Purpose: To provide the Commission with responses to the comments of Chairman Hendrie and Commissioner Gilinsky transmitted by memorandum from the Secretary to the Executive Director for Operations.

Category: This paper covers a major policy matter.

Issue: Whether NRC should regulate naturally occurring and accelerator produced radioactive materials.

Discussion: Background

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to regulate naturally occurring and accelerator-produced radioactive materials. On March 4, 1976, the Commission approved formation of an internal task force to review this matter (SECY-76-20).

Contacts:
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427-4130

Joel Lubenau, SP
492-7767

Discussion: (continued)

The task force report was published in July, 1977 (NUREG-0301) and a Federal Register notice was published and a news release was issued announcing its availability and inviting public comment for a sixty-day period. The report was given wide distribution.

A report on the public comments was furnished to the Commission on April 14, 1978 (SECY-78-211). The staff recommended that NRC seek legislative authority to:

A. License and regulate NARM as follows:

1. In any activity that is part of, or in support of, the nuclear fuel cycle regulated by NRC.

2. In any activity where: (a) NARM is manufactured (e.g., production of accelerator radioisotopes, the separation of radium and radium daughters, and radon generators); (b) NARM is incorporated into sources or devices* subject to licensing; or (c) NARM is used in the same manner as radioactive materials** subject to NRC regulation.

3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing. (It is intended that this include only activities where the introduction of NARM is deliberate and has as a purpose the utilization of its radioactive properties.)

4. In any activity involving the management of NARM wastes which result from licensed activities.

B. Extend authority under Section 274 of the Atomic Energy Act to relinquish authority to regulate NARM (except control of the distribution of NARM to persons exempt from licensing) to Agreement States and to other States having existing regulatory programs for NARM which are determined to be adequate and to be compatible.

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* e.g., sealed sources such as gauging devices, radiography sources, oil well logging sources and devices, etc.

** Radioactive materials used in normal form or loose form as, for example, in medical diagnosis.

Discussion: (continued)

On April 26, 1978, the staff briefed the Commission on SECY-78-211 at an open session.

Following the briefing the paper was returned without Commission action. Chairman Hendrie and Commissioner Gilinsky provided comments which the staff was requested to respond to when the paper was resubmitted (Enclosure A). The staff's responses are attached (Enclosure B).

The primary purpose of this paper is to provide the staff's responses to Commissioner comments on SECY-78-211. The pros and cons of such an action as well as other possible alternative actions were discussed in SECY-78-211, Appendix A.

A central issue in both Chairman Hendrie's and Commissioner Gilinsky's question concerned the significance of health and safety hazards from NARM.

Because there are gaps in regulatory control of NARM, data on the uses of NARM, incidents, and overexposures is fragmentary and incomplete. Thus, there are no adequate data available which can be used to create statistics on NARM uses and incidents that are, of and by themselves, convincing that the present regulatory scheme in the United States for NARM is either adequate or inadequate. The very deficiencies or gaps in present regulatory control of NARM preclude accumulation of data that could convincingly demonstrate that significant health and safety problems exist. The NARM Task Force was aware of this dilemma at the earliest stages of its deliberations.

The staff believes that the potential hazard from the use of NARM materials is at least as great as it is from NRC regulated materials which are used for comparable purposes. Further, there are no national or State-wide programs in operation except for the Agreement States which regulate the use of NARM materials to the same level as byproduct materials subject to NRC regulation. The data that are available, however, indicate that overexposures and unnecessary exposures are occurring from NARM. Although somewhat speculative, the staff concludes that this lack of regulatory control leads to a somewhat greater risk in the case of NARM materials. Radium constitutes a particularly troublesome problem because of its radiotoxicity (equivalent to plutonium), long half-life (1625 years), gaseous radon daughter and high energy gamma emission (similar to cobalt-60).

Discussion: (continued)

Regarding questions concerning the need for NRC to regulate NARM and of the roles of the other Federal agencies and states, the fact that the states have turned to the NRC for leadership indicates that problems remain. At the Agreement States meeting held October 3-5, 1978, the Agreement States repeated their request that the NRC actively seek the necessary legislation to regulate NARM. The staff continues to believe NRC is uniquely qualified to fill the Federal regulatory role for regulation of NARM because of its licensing system which is already in place and demonstrated to be effective.

Chairman Hendrie's final question about the ability of NRC to regulate NARM in view of recent problems experienced in our radioisotopes licensing program is an important issue. Progress has been made in recent months in improving the efficiency in radioisotopes licensing and we expect progress to continue. Given appropriate resources, the NARM program could be accommodated. However, if we were to be given responsibility for NARM without an increase in resources, there would be a very deleterious effect on the entire program.

Recommendation: The staff continues to agree with the task force recommendation that NRC seek legislative authority over NARM. Specific staff recommendations to accomplish this are set out for Commission approval in SECY-78-211, p. 7.

Coordination: The Offices of State Programs, Inspection and Enforcement, and Standards Development concur in this paper. OGC has no comments. The Office of the Executive Legal Director has no legal objections to the contents of this paper. The Director, Office of Nuclear Material Safety and Safeguards does not agree with the recommendation and his views are set forth in a separate paper.

Lee V. Gossick
Executive Director for Operations

Enclosures:
See next page

Enclosures:
A - Commissioner Comments on SECY-78-211
B - Staff Responses to Commissioner Comments
on SECY-78-211

Note: Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. _____.

Enclosure A

Commissioner Comments on
SECY-78-211

NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE SECRETARY

June 30, 1978

Rehm
Nussbaumer
Lubenau
Shapar
Minogue
Volgenau
Haller
Hayden
Hanauer

MEMORANDUM FOR: Lee V. Gossick
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-78-211 - "FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)"
(Commissioner Action Item)

Chairman Hendrie and Commissioner Kennedy have non-concurred in the recommendations of the staff. Commissioner Bradford has requested that the matter be reconsidered by the full Commission. Commissioner Gilinsky would like to see the staff gather information on incidents and risks associated with the use of radium and other NARM isotopes from those States now regulating such material, revise the paper accordingly and resubmit it.

The paper is being returned without Commission action at this time. When the staff resubmits the paper for consideration, the issues raised by Chairman Hendrie (attached) and Commissioner Gilinsky should be fully treated in order that these issues can be properly considered.

The tentative date for completion of these actions is September 1, 1978, or sooner, after reconstitution of the entire Commission.

Enclosure:
As stated

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
Acting General Counsel
Director, Policy Evaluation
Director, Congressional Affairs
D. Nussbaumer, NMSS
J. O. Lubenow, SP

CONTACT:
S. J. S. Parry (SECY)
634-1410

Chairman Hendrie's Comments on SECY-78-411 - Proposed Regulation of NARM

1. I am unconvinced that a case has been made that NRC licensing of NARM, as proposed, is necessary from a health and safety standpoint. In particular, what is the magnitude of overexposure now occurring from these sources that would be prevented by NRC licensing? Note that our licensing of byproduct materials does not prevent overexposures from careless handling: the same would be true for NRC-licensed NARM.

2. How would the proposed legislation be made compatible with the assorted existing laws across which it would cut? It appears to me that the proposal would complicate and further fragment an already complex set of authorities and agency responsibilities.

3. I do not see that the FDA/State voluntary NARM guidelines program has had time to become fully operative, so that a fair judgment can be made of its effectiveness.

4. Since it is unlikely that NRC would ever be assigned sole authority for all Federal regulatory activity for radioactive materials, why should we attempt to move into an area unrelated to our primary responsibility for nuclear fuel cycle-related matters? This seems especially unattractive to me since it requires that we seize authority from other Federal agencies who object to the attempt.

5. Finally, I am unconvinced that our byproduct material licensing effort is in such satisfactory shape that we should look for new materials of similar kind to add to the licensing list there.

Enclosure B

Staff Responses to Commissioner

Comments on SECY-78-211

Staff Responses to Commissioner Comments on SECY-78-211

Background

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to bring naturally occurring and accelerator-produced radioactive materials under its control. In response, the Commission created an internal task force to review the matter. The task force assessed the need for, and feasibility of, the Federal Government regulating naturally occurring and accelerator-produced radioactive materials. The task force examined the existing State and Federal programs concerning these materials and attempted to assess their effectiveness and reviewed existing rules and regulations, the sources and uses of materials (including wastes), and available information on incidents involving these materials.

The conclusions of the task force were (1) there are significant health and safety problems that arise from the present use of NARM, (2) there is a need for increased Federal involvement in regulating NARM, and (3) the NRC should seek legislative authority to regulate NARM.

1. Comment

I am unconvinced that a case has been made that NRC licensing of NARM, as proposed, is necessary from a health and safety standpoint. In particular, what is the magnitude of overexposure now occurring from these sources that would be prevented by NRC licensing? Note that our licensing of byproduct materials does not prevent overexposures from careless handling: the same would be true for NRC-licensed NARM. (Chairman Hendrie)

[I] would like to see the staff gather information on incidents and risks associated with the use of radium and other NARM isotopes from those States now regulating such material, revise the paper accordingly and resubmit it. (Commissioner Gilinsky)

Response

As noted in the staff paper, we do not have good documentation about overexposures from NARM, and for those cases which are documented, we can only speculate about what would have happened had NARM been subject to regulation. The staff agrees that no amount of regulation will preclude all careless use of materials. Regulation does, however, offer potential for reducing overexposure or unjustified exposure through a systematic evaluation system which controls the uses of materials, the design of equipment and facilities in which the materials are used, operating procedures, transfer to others and disposal as radioactive waste.

The available data indicate that both overexposures and unnecessary exposures are occurring from NARM. Some recent (1974-1978) incidents involving NARM have been:

o A patient receiving radiation therapy for cervical cancer had two radium applicators implanted. Subsequently, the attending physician removed only one although both were scheduled for removal. No surveys were made of the patient

to confirm all sources were removed. The second applicator (containing 60 mgm of radium) was then noticed to be missing from inventory one month later and traced to the patient. It was then removed. The dose to the cervix was estimated to be 220,000 rads. Of members of the patient's family and friends, a dozen persons received an average of 200 mrem whole body dose with a maximum of 5 rem (1976).

NRC requires a radiation survey of the patient and room to assure that all sources are accounted for.

- An investigation into the history of a 50 mgm source brought to a hospital disclosed that for three months previously, it was stored in a bedroom of a private residence. The whole body dose for one family member for the three months period was estimated to be 10 rads with lesser amounts to other family members (1977).

  NRC requires accountability of sources and evaluates safety of storage areas as part of the license process.

- As a result of improper storage of radium, a hospital secretary received an estimated whole body dose of 5 rem (1974).

  NRC evaluates safety of storage areas as part of the license review.

- The Denver, Colorado office of GSA put up for bids a moisture gage containing a 3 mCi Radium-Beryllium source as a Federal surplus item. A Colorado citizen, believing it to be a radiation counter and small calibration source successfully bid on it. It was transferred to him by GSA even though he did not possess

a State license to possess the radium. He has had no radiation safety training in handling this device. He recognized, however, the potential hazard to an untrained individual handling it and contacted the State for assistance in disposing of it. No excessive exposures to members of the public are known to have occurred; however, the incident served to illustrate the potential problems resulting from the present practices of the Federal Government in surplusing NARM (1978).

NRC requires that licensed material be transferred only to a person authorized to possess it. Transferor must make this determination prior to transfer.

- Personnel in a hospital handling 2-20 mgm radium sources failed to follow procedures. One individual received a skin dose of 73 rads (1976). NRC would require description of steps to be taken to prevent a recurrence, e.g., re-instruction.
- A 10 mgm radium plaque broke while being used for therapy in a large clinic. The entire clinic was shut down for two days and portions of the clinic were shut down for up to three weeks for decontamination. In some cases, portions of walls and floors as well as equipment were removed and disposed of as was some duct work. The cost was estimated to be $70,000, not including the costs incurred from the shut down of the clinic's facilities. More serious problems, such as spread

of the contamination outside the building were narrowly averted by the actions of an x-ray technician who was called from an adjacent hospital shortly after the source was broken. He quickly instituted appropriate steps to contain the contamination and the contaminated personnel. The source was made at least 35 years ago, was never registered with the State, and was never leak tested (1977).

NRC evaluates adequacy of sealed source design and requires that sealed sources be checked for leakage periodically.

The last case is reminiscent of the Americus, Georgia case in 1964 when a hospital was contaminated following a radium incident. The x-ray department was shut down for three weeks. Government agencies assisted the decontamination. If commercial services had been used, it was estimated it would have cost $100,000. Another contamination incident which occurred in 1968 involved a hospital in Pennsylvania. This hospital became contaminated with radium when a resident mishandled radium sources in a medical applicator and broke one source. A total of 17 55-gallon drums and one large crate of radium contaminated wastes were generated from the cleanup.

While these reports clearly show that when NARM is improperly handled there can be significant overexposures, similar incidents occur

for NRC-regulated materials. With better regulatory control, some NARM incidents might not have occurred. For example, there are very few cases of source failure in NRC's regulatory program because of stringent requirements for source design. Our principal source of information about NARM incidents is from the Agreement States which regulate these materials. The situation in states which do not regulate NARM is speculative. David Lacker, Administrator of Texas' Radiation Control Program provided the following comments to the NARM task force (NUREG-0301, pp. 20-21):

"These [NARM] incidents [in Texas] represent to me a serious potential hazard since they occurred in a regulating State. What happens in those areas of the country where there are essentially no regulations requiring the usual radiation safety precautions?... It seems to me that we must recognize that NARM, particularly radium, in the non-regulatory States probably is in much wider use than in States with regulatory programs. The reporting of incidents such as the areas I have cited is not required therefore we must assume that the potential for serious injury is greater in that contamination and other exposures could go on for extended periods of time."

This view is supported by the reports by States of initial inspection findings when NARM regulatory programs were implemented. For example, Pennsylvania, a non-Agreement State which has a strong licensing and inspection program for NARM inaugurated an intensive regulatory effort for 54 private medical practitioners using a total of 1.8 grams of radium. None of the users had performed an annual leak test and of the 54 users, 25 possessed sources which were suspected of leaking or were contaminated. Leaking or contaminated radium sources have been found in medical facilities at rates ranging from 13 to 53% in surveys by Alabama, Georgia, Indiana, Kansas, Kentucky, Minnesota, and New York.

Other health and safety problems were also found. The Pennsylvania survey showed 46% of the users failed to provide adequate security and shielding for storage. In Wisconsin, a study of 39 medical facilities using radium disclosed radiation levels from the radium in uncontrolled areas up to 100 mrem per hour and in four facilities, estimated that workers in unrestricted areas may have received more than 500 mrem in a year, the radiation protection standard for individual members of the public.

2. Comment

How would the proposed legislation be made compatible with the assorted existing laws across which it would cut? It appears to me that the proposal would complicate and further fragment an already complex set of authorities and agency responsibilities. (Chairman Hendrie)

Response

By defining NARM as byproduct material it would be exempt from most other Federal statutes. Actually the proposed legislation, carefully constructed, would simplify the regulation of NARM. Under the proposed legislation, any person proposing to possess or use radioactive materials will be subject to licensing requirements of either NRC or an Agreement State, regardless of the isotope, its origin, or place of use.* This will be a significant simplification of the present regulatory picture by placing uniform requirements upon all users of radioactive materials.

Today, to determine if you need a license to use radioactive materials, one must first determine if the material is byproduct, source, or special nuclear material. If it is, it is subject to NRC or Agreement State licensing. If it is not, one must determine what State it is being used in. In 30 States, licensing requirements apply. In 13 States, the sources need to be registered. In 7 States, there are no requirements being applied.

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* Radioactivity occurring in-situ, in mineral industries where its presence is incidental, or is an incidental contaminant present in products, (e.g., building materials) would not be covered by the legislation contemplated.

Regarding regulation of the workplace, if the material is byproduct, source or special nuclear material, a user in compliance with NRC or Agreement State regulations is deemed to be in compliance with OSHA requirements (in effect, exempt from OSHA). Users of NARM are not exempt from OSHA regulation, but OSHA does not license NARM. Federal users of byproduct, source and special nuclear materials are subject to NRC license requirements (except for certain DOD and DOE activities). Federal users of NARM are not subject to any licensing requirements.

3. Comment

I do not see that the FDA/State voluntary NARM guidelines program has had time to become fully operative, so that a fair judgment can be made of its effectiveness. (Chairman Hendrie)

Response

The staff does not believe the FDA/State voluntary NARM guidelines program will ever be as effective as a regulatory program. A detailed analysis of this program was made in SECY-78-211, pp. F-4 and F-5. The essential ingredient of this program is also its flaw: It is voluntary. It is not now fully effective because one key State Agency - New York State Department of Labor, because of budgetary reasons - is not actively participating. This is significant because Radium Chemical Co., a major and possibly the largest supplier of radium in the U.S., is located in New York. The sealed sources it distributes nationally and internationally have

not been evaluated by the State Department of Labor with respect to adequacy of design, fabrication and quality controls for manufacture.

This is a potentially significant deficiency. The Agreement States' experiences with NARM suggest that there is a higher incidence of leaking NARM sources than for sources fabricated using agreement materials. In part, this reflects the presence of NARM sources, particularly older radium sources, which would not meet current standards for fabrication and whose manufacture would not meet current requirements for quality controls that are applicable to agreement material sources.*

The problem, however,is not limited to radium. James Blackburn, from Illinois, a non-Agreement State which licenses NARM, recounted his experience with a Co-57 source, (an accelerator-produced isotope):

> "A recent search for the manufacturer of [this] source revealed that the source had been labeled and sold by a minimum of 3 different firms. Each time the source was sold it changed regulatory jurisdiction. This entire sequence occurred before any competent regulatory agency had even documented the existence of such a source. Without pre-marketing evaluation and clearance, the entire regulatory program governing the distribution of radioactive sources becomes marginal."

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* The problems created by lack of Federal manufacturing standards for sealed NARM sources are more fully discussed in NUREG-0301. See pp. 10-13.

The use of accelerator-produced radioisotopes is increasing very rapidly, especially in medicine and frequently as substitutes for NRC regulated isotopes. FDA has actively pressed for the substitution of I-123 for I-125 and I-131 to reduce patient dose in certain diagnostic procedures. The Wall Street Journal, on July 27, 1978, reported that New England Nuclear expects its sales of Tl-201 to increase to "'well over $5 million' this fiscal year, up from about $2 million in fiscal 1978. About 400 hospitals are using it, up from 200 last December." The company has 2 cyclotrons, is installing a 3rd, and is planning to build a linear accelerator.

In Pennsylvania, of 302 licenses for medical users of NARM, 260 include authorizations for accelerator-produced isotopes. In New Jersey, there has been recently a 40% increase in NARM licenses, mostly to authorize accelerator-produced isotopes.

The FDA/State voluntary NARM guidelines program has been an interim asset to states that have chosen to establish regulatory, and in particular, licensing programs for NARM. However, there are no incentives that would cause development of minimal state programs nor is there any program to assure maintenance of adequate state programs. Further,

this program does not cover areas that need Federal - not State - action for effective control: Importing and exporting of NARM, supplying of NARM by Federal Agencies (including surplusing) and transfer of NARM in interstate commerce; e.g., as consumer products.

4. Comment

Since it is unlikely that NRC would ever be assigned sole authority for all Federal regulatory activity for radioactive materials, why should we attempt to move into an area unrelated to our primary responsibility for nuclear fuel cycle-related matters? This seems especially unattractive to me since it requires that we seize authority from other Federal agencies who object to the attempt. (Chairman Hendrie)

Response

The potential hazards arising from the use of NARM are similar to those arising from the use of byproduct material in medicine, research and industry. Regulation of NARM would be similar to the regulation of byproduct material. The main reason for NRC assuming control of NARM is that it has a regulatory system in place which has been demonstrated to work fairly well. This apparently is the reason the states have asked the NRC to step into the picture. Although incidents do occur with byproduct materials, the number of reported incidents is relatively small in relation to the size of the program (e.g., approximately 37,000 patients treated per day with byproduct materials).

With respect to other Federal agencies, 22 were identified by the task force as having potential regulatory interests in NARM.* Of these, only two expressed objections to the proposal that NRC seek legislative authority to license NARM.* EPA felt it had sufficient existing authority and FDA, while endorsing as a long term goal increased Federal regulatory control, recommended deference be given to their voluntary state program.

5. Comment

Finally, I am unconvinced that our byproduct material licensing effort is in such satisfactory shape that we should look for new materials of similar kind to add to the licensing list there. (Chairman Hendrie)

Response

This is a very important issue. There is no question that the efficiency of the radioisotopes licensing process must be improved. We have taken a number of long-term measures to improve efficency and have taken some additional steps to reduce the licensing backlog in the interim. Among the long-term measures are a reorganization of the radioisotope licensing function to give greater emphasis to license reviews, request for and partial granting of, additional

* See SECY-78-211, pp. D-1 and 2 for list. These agencies were sent copies of the Task Force report under cover of a letter from the Task Force Chairman asking for comment. Seven responded; five expressed support.

manpower for FY79, and a contracted paperflow study to identify ways of improving and streamlining the license support activities. The short-term steps to reduce backlog include establishment of a special licensing task force to augment the radioisotope licensing staff and use of overtime by the regular staff. As a result of the short-term measures, the number of applications for new licenses and amendments pending NRC review for more than 90 days is being reduced. In addition, the licensing task force completed review of over 300 license renewal applications, a significant portion of the renewal backlog.

The key here is that we must improve efficiency, regardless of whether or not we regulate NARM. We do not believe that the addition of NARM would make a substantial difference in the outcome of this effort provided that adequate resources are made available for the increased workload. If, however, we obtained legislative authority over NARM without an appropriate increase in resources to do the job, our ability to carry out our present radioisotope licensing responsibilities would be severely impacted.

ENCLOSURE 2

For: The Commissioners

From: Clifford V. Smith, Jr., Director
Office of Nuclear Material Safety and Safeguards

Thru: Executive Director for Operations

Subject: NMSS POSITION ON RECOMMENDATIONS OF TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM) (SECY-78-211)

Purpose: To provide the Commission with further analysis and a revised NMSS position on the NARM Task Force recommendations.

Category: This paper covers a major policy issue.

Discussion: SECY-78-211 recommended that the NRC seek legislative authority to license and regulate NARM. NMSS concurred with the recommendations. SECY-78-211 was returned without Commission action. Chairman Hendrie and Commissioner Gilinsky provided comments and raised questions about the paper (SECY Memo dated June 30, 1978).

In addition to having the NARM Task Force prepare responses to the Commissioners' comments, the Director, NMSS, requested Mr. Richard E. Cunningham, Acting Director, Division of Fuel Cycle and Material Safety, to independently evaluate the merit of the recommendations in SECY-78-211 in view of questions raised by the Commissioners. Cunningham's analysis is contained in the enclosure. The Task Force responses to the Commissioners' comments are being forwarded by the EDO.

Cunningham's memorandum raises two important issues:

a. Resources

The resource requirements to bring NARM under NRC regulatory control might be far in excess of that projected in SECY-78-211.

Contact:
R.E.Cunningham, FC
42-74485

b. Policy

An NRC program to regulate NARM would expand the NRC regulatory role from that of assuring safety in nuclear fuel cycle and power production activities to that of a "radiation protection agency." This raises questions about where to logically draw the line (e.g., NARM, x-rays, etc.) in view of limited NRC resources and responsibilities of other Federal and state agencies.

Recommendations: Because of the issues raised in Cunningham's memorandum, the Director, NMSS, recommends that the Commission consider the following as an alternative to adopting the recommendations in SECY-78-211:

a. Forwarding the findings of the NARM Task Force to Federal agencies, State governors and Congressional committees having responsibilities in this area.

b. Offer NRC assistance in developing model control programs based on our regulatory experience in the byproduct materials program.

c. Review NARM control programs in a few years to determine if progress is made and whether further NRC action might be appropriate.

Clifford V. Smith, Jr., Director
Office of Nuclear Material
Safety and Safeguards

Enclosure:
Memo fm R.E.Cunningham

NOTE: Commissioner comments should be provided directly to the Office of the Secretary by close of business

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 2 1 1978

MEMORANDUM FOR: Clifford V. Smith, Jr., Director
Office of Nuclear Material Safety and Safeguards

FROM: Richard E. Cunningham, Acting Director
Division of Fuel Cycle and Material Safety

SUBJECT: STAFF RESPONSES TO COMMISSIONER COMMENTS ON THE FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM) (SECY-78-211) (SECY MEMO DATED JUNE 30, 1978)

The NARM Task Force has prepared responses to questions raised by the Commission regarding the NRC seeking legislative authority over NARM. Some members of the FC staff as well as other NRC staff and state officials hold strong views that the NRC should seek legislative authority over NARM as recommended in SECY-78-211. This memorandum responds to your verbal request to take an independent look at the situation.

The staff paper responding to questions raised by Commissioners has attempted to elaborate on the risks from NARM and the benefits that might accrue from NRC exercising regulatory control over NARM. Although the information provided is not as precise as either we or the Commission would like it to be, I believe the staff has gone about as far as it can to gather information without significantly increasing expenditure of resources on the study. Data gathering in the absence of some regulatory leverage to acquire further information is particularly difficult.

There is no doubt in my mind that NARM materials are at least as hazardous as byproduct materials which we currently regulate. Also, the protection of the public health and safety would be enhanced over that which is provided by current voluntary Federal programs and state programs if the NRC were to regulate NARM. Whether it would be worth the cost is difficult to say. I believe, however, the staff in its analysis has greatly underestimated both the problems it would encounter in mounting a regulatory program for NARM and its cost.

The resource requirements estimated by the staff, which are relatively small, did not include the additional effort that would be needed initially to bring the program under control. I believe the initial effort could be significant and offer the following observations:

1. Radium has been used in this country for approximately 75 years; often carelessly by today's standards. Once we embark on a program to regulate radium, I am sure that we will find old leaking sources, contaminated buildings, etc., which will embroil us in a substantial cleanup campaign with all the technical and administrative work this requires. This work would be complicated because many of the radium users will have disappeared from the scene leaving complex legal problems about financial responsibility for cleanup.

2. The radiotoxicity of radium is roughly equivalent to that of plutonium and it has a long half-life. Therefore, by current thinking, concentrated radium wastes should be placed in an HLW or TRU repository. Since we do not have a repository, it would be necessary to develop a program for interim safe storage.

3. The distinction between regulating accelerator produced radioisotopes and regulating the accelerators themselves is very marginal. In the past, we have evaluated shielding around accelerators which used licensed tritium targets although the licensed material itself (tritium) could not contribute measurably to worker dose. In the case of accelerator produced NARM, there is a close coupling of the accelerator and its radiation hazards, to that of the NARM itself in terms of the facilities and workers involved. In the course of licensing accelerator NARM, we would undoubtedly become involved in the safety evaluation of the accelerator. We are not currently organized to deal with accelerator safety problems.

These observations do not diminish the importance of NARM control. In my opinion, however, seeking regulatory control over NARM would embark the NRC on a major program requiring substantial resources. The legislation would not only need to deal with the authority question but contain provisions for financing cleanup of contaminated sites and storing wastes. If resources to do the job were not provided with the legislation, our ability to discharge existing responsibilities with today's tight budget would suffer badly. It is difficult to estimate the resources that would be required to regulate NARM as proposed in SECY-78-211 because we do not know the full dimensions of the problem. However, my guess is that it would be somewhere between 15-25 man-years/year (plus

funds for various studies) for about the first five years until the problem is brought under control; following which requirements would taper off to a level required for maintenance of the program.

There is also a major policy question associated with the proposal in SECY-78-211. Heretofore, the NRC's regulatory authority, and that of its AEC predecessor, has been confined to activities associated with the nuclear fuel cycle. This includes the radioisotope byproducts of the nuclear fuel cycle used in medicine, industry, etc., as well as the new legislative authority over radium in mill tailings which is a byproduct of a fuel cycle operation. A movement to regulate NARM would be a major departure from the NRC's existing regulatory role. It would involve the NRC in an area where the states traditionally have responsibility for protection of the public health and safety. This would run counter to our broad program direction of attempting to have the states assume greater responsibility for regulation of byproduct materials where state and local issues rather than national issues are involved. It would also raise an open-ended question of where to draw the line logically. The public is exposed to a number of radiation sources in addition to those which we currently regulate and NARM. Exposure to x-rays is an outstanding example. While some states have good programs to control these other sources, not all do. There are also national programs to control these other sources which are roughly equivalent to the national programs for NARM but they are not as rigorous as an NRC program would be.

In view of (a) the potential resource requirements to regulate NARM, (b) the tight budget, (c) our present commitments in materials licensing and waste management which will be difficult to meet, and (d) the broad policy implications of embarking on such a course, I believe it would be prudent to reconsider the recommendations contained in SECY-78-211. More specifically, I suggest that we do not pursue the legislative proposals recommended in SECY-78-211 at this time. Rather, the NRC should bring its findings to the attention of Federal agencies currently responsible for health and safety in this area, appropriate Congressional committees, high level state officials, the Conference of State Governors, etc. to encourage more rigorous action on their part. The NRC could offer assistance in developing model control programs based on our regulatory experience in the byproduct materials program. The

NRC might reexamine the situation in a few years to determine if improvements have been made and whether legislative initiatives might be appropriate at that time.

Richard E. Cunningham
Acting Director
Division of Fuel Cycle
and Material Safety